UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-12257-PBS Judge Patti B. Saris
THIS DOCUMENT RELATES TO: ALL ACTIONS	

AMENDED DECLARATION OF DIRECT TESTIMONY OF DR. SUMANTH ADDANKI[1]

I, Sumanth Addanki, Ph.D., declare that:

I. Qualifications

1. I am an economist and a Senior Vice President at National Economic Research Associates, Inc. (NERA). I hold AM and Ph.D. degrees in economics from Harvard University and have specialized in the study of industrial organization. I have published articles on industrial organization economics and have written articles on antitrust issues for the American Bar Association (ABA) and other like institutions. These institutions have also invited me to lecture and comment on the market impact of various marketing, pricing and intellectual property strategies employed by firms, in general as well as specifically in the pharmaceutical industry. I have testified by invitation before the Federal Trade Commission (FTC) on the analysis of competition in high technology industries.

[1] The only additions to this testimony are found in paragraphs 68 through 70 and Tables 1 and 2; I incorporate all my previous exhibits, appendices, addendums etc. by reference. Because my testimony relates to and builds upon my prior Declarations and Report in this matter, I incorporate those documents by reference as well.

2. I have consulted on many antitrust, intellectual property and commercial damages cases involving different industries, including agriculture, airlines, computer hardware and software, electronic components, health care, newspaper, office products, oil and gas, tobacco, and tools and hardware among many others. In addition, I have consulted extensively in the pharmaceutical industry, analyzing the market impact of various pricing, marketing and intellectual property strategies; assessing the impact of mergers and acquisitions; studying the effect of suppressed or delayed generic competition; and assessing economic damages, among other assignments.

3. Some of my consulting assignments have led to my being qualified as an expert economist in Federal courts and testifying in those courts as an expert in the economics of industrial organization. I have also testified on the appropriate analysis of pharmaceutical markets in proceedings before the FTC.

4. My *curriculum vitae,* which is appended to this report as Exhibit 1, includes a list of all my publications within the preceding ten years and my testimony as an expert at trial or in deposition within the preceding four years.

5. For my services in this matter, Schering-Plough is being billed by NERA Economic Consulting at my hourly rate of $595.

II. Scope of Engagement and Investigation

6. Counsel for Schering-Plough Corporation ("Schering") and Warrick Pharmaceuticals Corporation ("Warrick") have asked me to analyze economic issues raised by various claims

that the plaintiffs have advanced in this litigation, as well as to evaluate the opinions offered by the plaintiffs' economic experts, Drs. Hartman and Rosenthal. Specifically, I was asked to assess and comment upon: (1) whether Warrick and Schering had the incentive to, and did, manipulate AWP, as the plaintiffs and their experts assert; and (2) the methodology that the plaintiffs employ to assess liability and damages with respect to the Warrick and Schering drugs at issue.

7. In preparing this testimony, I (and economists working under my direction) have reviewed information from a variety of sources. These include documents produced in the course of this lawsuit, information from publicly available sources, deposition testimony, and discussions with company personnel. In addition, I have relied on my experience and training as an applied microeconomist and my experience in analyzing the pharmaceutical industry.

III. Summary of Opinions

A. Executive Summary

8. None of the Schering or Warrick drugs fit the plaintiffs' theories of AWP manipulation. The plaintiffs' theory of liability is principally a theory that, in settings in which physicians both prescribe and dispense drugs, there could be an incentive to inflate the AWPs of those physician-dispensed drugs to increase net reimbursement to the physician and thereby influence his or her choice of drug. The Schering and Warrick drugs do not fit this theory for three reasons. First, no incentive to inflate AWPs exists for the Schering and Warrick drugs. This is because they are dispensed by pharmacies and are largely self-administered. Thus, the physician is not reimbursed for the drug and has no pecuniary interest in which drug is

chosen. In addition, for the Schering branded drugs, the entity with an economic interest in reimbursement—the pharmacy—has no ability to choose the drug that is dispensed; it must dispense the drug that is prescribed by the physician.

9. Second, as the Court has already noted, pharmacy-dispensed drugs are subject to market forces from other market participants that cause highly transparent pricing. Thus, another key element of plaintiffs' theory, secret discounting, simply does not exist. While Schering does have one drug—Intron-A—for which a minority of NDCs (6 of 27) may be physician-administered, it is clear that those NDCs are not singled out in any way for special treatment—their list prices and AWPs per unit are identical to those of the pharmacy-dispensed NDCs.

10. Third, there is also no incentive or ability to manipulate the AWPs of Warrick's generic drug, albuterol. The plaintiffs have conceded this point in the private market, acknowledging that the reimbursement of generics is generally constrained by MACs and is not a function of AWP. As to Medicare, the so-called "informal Nash equilibrium" theory makes no sense, as Dr. Rosenthal concedes. The plaintiffs argue that all of the manufacturers of albuterol within a J- code have an incentive to maintain an artificially high median AWP in order to influence pharmacy choice between albuterol and therapeutic competitors. However, as Dr. Rosenthal has acknowledged, pharmacies do not have a choice among therapeutic competitors; they must dispense the drug prescribed by the physician.

11. While there are other significant flaws and errors in the plaintiffs' theories and their experts' analyses, the reasons described above are sufficient to demonstrate that the plaintiffs' theories of manipulation do not meet any economically reasonable standard of viability for any of the accused Schering and Warrick drugs. For the Court's convenience, I summarize below the specific features that apply to each drug.

Summary Analysis of Accused Schering and Warrick Drugs

Supplier	Product	Dispensed By	Single- or or Multi-Source	Remarks on Plaintiffs' Claims of AWP Manipulation
Warrick	Albuterol Sulfate	Pharmacy	Multi-Source	The plaintiffs claim damages for Class 2. No economic incentive to manipulate AWP or "spread" because of single-price reimbursement. No evidence of AWP manipulation
Schering	Temodar	Pharmacy	Single-Source	The plaintiffs claim damages for Class 2. No economic incentive to manipulate AWP because prescribing physician has no pecuniary interest in "spread," and pharmacy must dispense what is prescribed. No evidence of AWP manipulation.
Schering	Proventil	Pharmacy	Initially Single, Multi-Source after Generic Entry	The plaintiffs claim damages for Class 2 and, through 1992, for Class 3. No economic incentive to manipulate AWP: during single source period, prescribing physician has no pecuniary interest in "spread"; during multi-source period, because of single-price reimbursement. No evidence of AWP manipulation.
Schering	Intron-A: Smaller Dosage Sizes	Pharmacy	Single-Source	The plaintiffs claim damages for Class 2. No economic incentive to manipulate AWP because prescribing physician has no pecuniary interest in "spread," and pharmacy must dispense what is prescribed. No evidence of AWP manipulation.
Schering	Intron-A: Large Dosage Sizes	Potentially by Physician	Single-Source	The plaintiffs claim damages for Class 2 and Class 3. Per-unit AWP identical to smaller, pharmacy-dispensed dosage sizes excluded from Class 3 by the plaintiffs. No evidence of AWP manipulation.

B. Summary of the Plaintiffs' Theory

12. It may be useful, before proceeding further, to summarize what the plaintiffs and Dr. Hartman have alleged. The essence of their claim, from an economic standpoint, boils down to this: when providers of pharmaceuticals are reimbursed for the drugs that they provide on the basis of the drugs' AWPs, manufacturers have incentives to, and do, artificially inflate the AWPs of their drugs to make them more attractive from the providers' standpoint. As evidence of this, Dr. Hartman calculates a "spread"—basically the difference between the AWP and the price actually obtained by the manufacturer—and uses it as a bellwether indicator of this alleged AWP manipulation: if the "spread" for a given accused drug is "too high" in his view, that is enough for him to conclude that there was manipulation of that drug's AWP. Then, he asserts that governmental payors such as Medicare—as well as third-party payors (TPPs) —were unaware of these "spreads" and were, therefore, paying much more in reimbursement than they would otherwise have paid for these drugs. Finally, he calculates damages.

13. The plaintiff's theory is simply inconsistent with the market realities of the pharmaceutical industry as they relate to the Schering and Warrick drugs. Moreover, their test is simply inappropriate, and most important, the Schering and Warrick drugs at issue here simply do not show any sign of the sort of AWP manipulation that the plaintiffs allege.

IV. The Plaintiffs' Test Based on "Spreads" is Inappropriate and Useless

14. To begin with, the plaintiffs' focus on spreads is misplaced, because spreads evolve naturally over time for reasons that have nothing at all to do with the type of AWP manipulation alleged. Recall that Dr. Hartman's spread is the difference between the AWP and the ASP—

the average price actually obtained by manufacturers. Note first that the AWP of a branded product is a direct function of its list price: if a drug wholesaler such as McKesson orders a product from Schering, that wholesaler will be charged the list price—sometimes called the wholesale acquisition cost (WAC) or net direct price (NDP)—which is formulaically related to the AWP so that AWP is 20 to 25 percent above WAC (there may also be a standard discount of 2.5 percent for prompt payment).

15. Next, let us consider what happens to a drug over its life. When new, it frequently represents a real improvement over existing therapies—perhaps even a medical breakthrough; as such, it has little, if any, therapeutic competition, so everyone who needs it gets prescribed it. Under these circumstances, there is no market pressure on the manufacturer to offer any discounts on the drug, and the price actually obtained by the manufacturer is probably quite close to the list price, the WAC, and the "spread" is going to be relatively small (i.e., essentially the "spread" introduced by the formulaic difference between AWP and WAC—20 to 25 percent).

16. As the drug ages, the competitive situation facing it will, inevitably, change. As with products in any market, the longer that the drug remains on sale, the more likely it is to have encountered entry from newer and better products, drugs that can do the same or better, therapeutically, as the aging drug. Then, the maker of this aging drug needs to make it more attractive to those ultimately paying for the drug; the most obvious way in which that is done, just as it is in so many other markets with which we are familiar in our daily lives, is via discounting. As the level of therapeutic competition increases, so does the discounting.

17. Note, though, that the discounting is *targeted*. Sales that are most sensitive to the price charged—i.e., where the customers' purchases are most responsive to such discounting—may be heavily discounted, even as many other sales may be made at or near list price. What this means, of course, is that it makes no sense simply to drop the list price. Rather, the discounting is targeted to where it will be most effective. And, that is exactly what we see in many other markets that are familiar to us as well. For instance, the list price of an airline ticket—the "Y" class undiscounted roundtrip coach fare from say, Boston to Miami—may be as high as $1,900; and, indeed, the business traveler who must fly at short notice may end up having to pay something very close to that fare. Other travelers, particularly budget-conscious vacationers and the like, will shop for—and find—much lower prices on the same "product": coach-class travel from Boston to Miami. Much the same situation exists in the case of hotel rooms, and there are many other examples of selective discounting that can be found in our daily lives; indeed, targeted discounting is very much a part of our economy.

18. Returning to the case of our (hypothetical) aging drug, its list price is not likely to be cut to meet competition, because some portion of sales will continue to be made at list price; its AWP will not fall, because it is, of course, formulaically related to the list price. Rather, the degree of targeted discounting will increase; as a consequence, its ASP will, inevitably fall, and the "spread" calculated by Dr. Hartman will, inevitably, increase. And, this will happen even if there has been no AWP manipulation of the sort alleged by the plaintiffs. It is simply a matter of market economics and arithmetic. Note, moreover, that these "spreads" will grow, in that case, because of increased discounting, which is nothing other than price

competition. Over a century of U.S. antitrust law and policy have explicitly recognized the value of price competition; it would be perverse, indeed, to condemn a product because its average price in the marketplace had fallen because of price competition.

19. Once generic competition enters the market, spreads grow even more rapidly because of increasing price competition; as generic prices decline, spreads as a percentage of price can become quite large, although the dollar spreads at issue are usually small relative to dollar spreads on branded drugs.

20. Thus, I conclude that one simply cannot infer anything meaningful about whether AWPs were manipulated by looking at "spreads" because spreads can be high even if AWPs were never manipulated as alleged. Indeed, they can be high purely because of the benefits of the very price competition upon which our economic and antitrust policies place such high value.

21. And, in fact, Dr. Hartman's claimed "liability" findings for the Schering drugs accused in this case—Proventil, Temodar and Intron-A—reveal the essential futility of his test. To begin with, each of the accused Schering products was sold predominantly at or near its list price, its WAC. This is presented in Exhibits 3A-C and 4. With the substantial sales being made at or near list price, it is easy to understand why Schering did not lower its list price—its WAC—but, instead, met competitive pressures using targeted, case-by-case discounting. Given that AWP is formulaically related to WAC according to industry standards, it is easy to see why Schering's AWPs were not lowered either. Thus, "spreads" of the sort calculated

by Dr. Hartman would, therefore, inevitably grow in response to competition, even if there were absolutely ***no*** manipulation afoot.

22. Second, Dr. Hartman's proposed "spread" test only finds "liability" in sporadic cases for the accused Schering drugs, indicating that the high "spreads" to which he alludes are the result of the natural market forces discussed above rather than any systematic manipulation scheme.

23. Finally, if "ASP" is recalculated more appropriately in light of Judge Saris's recent ruling, "liability" based on Dr. Hartman's approach largely vanishes, again illustrating the fundamental inadequacy of his approach. Judge Saris has ruled that AWP should be interpreted to mean the average price actually charged by wholesalers.[2] Of course, Schering—or, indeed, any other drug manufacturer—would not be privy to the prices that wholesalers actually charge for the products that they sell. However, it is reasonable to assume that the prices that they charge their customers are at least as high as the prices that the wholesalers themselves must pay. Therefore, I have calculated the average price that Schering charged for the accused products in its sales to full-line wholesalers, by far, the largest class-of-trade. This average price, of course, represents a lower bound on the prices actually charged by these wholesalers for products at issue.

[2]In Re Pharmaceutical Industry Average Wholesale Price Litigation, M.D.L. No. 1456, Memorandum and Order, Document 3299, November 2, 2006.

24. Exhibits 11A-D show the result of substituting this average price—the lower bound on an actual average wholesale price—in place of Dr. Hartman's "ASP". Strikingly, Dr. Hartman's findings of "liability" based on his "30 percent screen" largely vanish as a result.

25. In light of the foregoing, it should be clear that tests based on "spreads" are essentially useless. Therefore, I will suggest below a more appropriate test for AWP manipulation, one that is more capable of answering the question of whether AWPs were manipulated in the manner suggested by the plaintiffs. First, however, I will explain why, for the majority of drugs, the plaintiff's theory makes no economic sense whatsoever.

V. The Plaintiff's Theory Makes No Economic Sense

26. Again, the plaintiffs assert that Schering and Warrick artificially inflated the AWPs of the accused products so as to make these products more attractive to providers so that those providers would choose to supply those products rather than alternatives.

27. It will be useful to pause here and sketch out how drugs actually reach their ultimate consumers—the patients. For most self-administered drugs, the physician writes a prescription, which is then filled by a pharmacy. When there are a number of therapeutic alternatives available, the physician may select a remedy based, in part, upon the nature of the patient's insurance coverage, but the physician has no economic incentive connected to the AWP of the drug, so even if the AWP were being manipulated, it would not have affected the choice of drug prescribed.

28. Once the drug is prescribed, if it is a branded drug, there is little, if anything, that the pharmacy can do but dispense the drug prescribed, regardless of the relative attractiveness or unattractiveness of the AWP of that drug. The pharmacist cannot substitute another product simply because its AWP is "more attractive."

29. Things are a little different when the prescribed drug is generic or has generic substitutes. Then, assuming no explicit instruction from the physician to "dispense as written," the pharmacy can choose from among the same product offered by a variety of different generic suppliers.

30. Might this be an area where AWP manipulation of the sort alleged by the plaintiffs makes sense? Not generally, because when there are multiple sources of generic alternatives available, reimbursement for ***all*** of those products is frequently based on a ***single*** measure, ***not*** the individual products' own AWPs! So, even if manipulation by a manufacturer resulted in changes in the reimbursement, which would be difficult for any individual manufacturer to effect, that change would apply to ***all*** the products, resulting in no advantage to the manufacturer who manipulated its AWP. Therefore, reimbursement based on measures like MAC, FUL, medians, and so on, ensure that no individual generic product can gain a competitive advantage by raising its AWP! Appendix A discusses this in more detail and also illustrates the difficulty, in any event, of attempting to manipulate a reimbursement measure like the median AWP.

31. So, for products that are prescribed by the physician and dispensed by a pharmacy, there is little scope for the alleged AWP manipulation to provide any competitive advantage for the products whose AWPs were allegedly manipulated. Of the Schering and Warrick products at issue, albuterol, Proventil, and Temodar are dispensed almost entirely in this manner. The only Schering product at issue that is administered by physicians to any significant extent is Intron-A, in the a limited number of larger dosage sizes; the AWPs of the smaller dosages, which are typically dispensed by pharmacies, are the same per unit as the AWPs of the potentially physician-administered NDCs. For these products, again, the plaintiffs' theory simply makes no economic sense at all: the sort of AWP manipulation alleged by the plaintiffs simply ***could not*** have offered any competitive advantage.

32. Although the plaintiff's theory of manipulation fails from the outset because it makes no economic sense generally, I have examined AWPs for the Schering and Warrick products at issue here to test directly for evidence of any manipulation of the sort alleged by the plaintiffs. For reasons that I have already explained, I do not test the plaintiff's theory using spreads because spreads can grow and be large for reasons having nothing to do with AWP manipulation. Spreads can be large purely because of price competition—exactly the sort of competition that our antitrust policies promote and foster.

VI. A More Appropriate Test for Manipulation

A. Overview

33. In light of this, the right approach to ascertaining whether a manufacturer had actually manipulated its AWP in the manner alleged by the plaintiffs is to look directly at AWP: did the AWP of the product at issue move in ways that suggest manipulation? For example, did

it exceed, or grow faster than, the AWPs of its competitors, particularly of competitor products that have NOT been accused in this suit. If it did not, it is hard to credit a theory of manipulation.

34. I have carried out exactly such an examination and have reviewed the history of the accused products' AWPs over time, an analysis that is reported more fully below. I find that the Schering products at issue compete in virtually every instance with therapeutic alternatives that are ***not*** accused and that have higher absolute AWPs or have AWPs that grow faster. Again, if the AWPs of the accused products were being manipulated as the plaintiffs allege, I would have expected them to have been higher, or to have grown faster, than the AWPs of all the therapeutic alternatives that have ***not*** been accused of AWP manipulation. That fact that the accused AWPs do not behave in this way indicates that there was no such manipulation going on, even for those few accused Schering products that might be dispensed by physicians. Likewise, the Warrick generic products at issue had AWPs that were largely static, unchanged from 1995 forward, not at the high end of the range of AWPs for the competitive set of generic products (accused as well as non-accused), and showed no evidence of responding to heightened competition in the manner implied by the plaintiff's theory (i.e., by raising AWPs relative to their competitors).

B. Temodar, Proventil and Intron-A

35. I should stress that I have carried out this analysis of AWPs for all of the accused Schering products, even though the fact that they are largely pharmacy-dispensed should obviate the need for any such inquiry—because there is simply no ***incentive*** to try to manipulate the AWP or "spread" for a pharmacy-dispensed drug. Of the three accused Schering drugs, only

one is administered by physicians to any appreciable extent: Intron-A, in the larger dosage sizes. Temodar and Proventil are almost entirely self-administered and dispensed through pharmacies. Proventil (and its generic equivalent albuterol sulfate) are reimbursed under Medicare Part B only because they are frequently administered with the use of a nebulizer—a piece of durable medical equipment typically rented from the pharmacy at which the prescription is filled—not because they are physician-administered.

36. The larger dosage sizes of Intron-A are sometimes infused by physicians at the onset of secondary treatment for melanoma, conyloma and AIDS-related Kaposi's Sarcoma; after the initial loading dose, it is injected by the patient using a "pen" purchased from a pharmacy. Not only do the AWPs for the potentially physician-administered NDCs move in a fashion inconsistent with the plaintiff's manipulation theory, ***all*** of the Intron-A AWPs—across pharmacy-dispensed as well as potentially physician-administered dosage forms—move in identical ways, strongly refuting any suggestion that Schering had "targeted" the potentially physician-administered Intron-A NDCs for AWP manipulation (see Exhibits 2A and 2B).

37. In light of the foregoing, it should be clear that Schering had no incentive to inflate the AWP of Proventil or Temodar: physicians who prescribe it could not profit from the "spread" in the manner that the plaintiffs suggest. Similarly, pharmacies could not dispense Temodar or Proventil to fill prescriptions for other drugs, and, therefore, could not have been motivated by "spreads" to dispense these drugs. Nor could pharmacies have been motivated by "spreads" to dispense Intron-A because they must dispense the drug when it is prescribed and only then; those dosage forms that may be dispensed by physicians were priced identically to the pharmacy-dispensed NDCs, contradicting any suggestion that Schering had targeted the

"physician-administered" NDCs for AWP "inflation." All three products are sold largely at or near list price (WAC), so any "spreads" are the inevitable result of targeted discounting (see Exhibits 3A-C).

38. To implement my direct test for AWP manipulation, I had to identify the therapeutic alternatives with which each accused Schering product competed, in order to evaluate whether the Schering product's AWP grew faster or otherwise outpaced the AWPs of non-accused competitors. I examined Schering's contracts with the trade to identify, for each accused Schering branded product, the therapies that were considered to be competitive with that product. The AWPs of the accused Schering products were then compared with the AWPs of those competitive products. Of course, with therapeutic equivalents, it is not necessarily the case that every NDC of a Schering product family competes directly with every NDC of each competitive product identified in the contracts. Nevertheless, the data reveal that for the vast majority of years, the accused Schering NDCs were outpaced in their AWP growth by another firm's competing product, simply below it, or, that the Schering AWP was not changing at all. Of the 39 branded Schering NDCs accused, only 6 have any years for which one or the other of these situations does not apply. See, again, Exhibit 8. Again, the direct evidence from AWP movements is clear: the data do not support the notion that Schering was artificially inflating the accused products' AWPs relative to non-accused products.

C. Albuterol Sulfate

39. I have compared the behavior over time of the AWPs for Warrick's accused albuterol NDCs with the AWPs of other, competing, albuterol products, both accused and non-accused. As

Exhibits 5A-B, 6A-C and 7A-B show, the data reveal no evidence that Warrick has either inflated its AWP or benefited from a high AWP. Warrick's AWPs for the accused albuterol products, 0.5% and 0.083%, have typically been among the lower-priced products of this type. The AWPs for these albuterol products are generally at or below the median of the prices of products with a similar product description.[3] Even though Warrick's albuterol products had relatively low AWPs, their products often had a large share of the sales for products with comparable descriptions. For example, Warrick had one of the top two market shares for albuterol 0.5% based on IMS data. Warrick's market share was the largest and over 40 percent from 2000 to 2002, falling in the next two years. Similarly, Warrick had the second largest implied market share for its albuterol 0.083% products from 2000 to 2003 based on IMS sales data, and the largest market share in 2004.

40. In addition to being relatively low, Warrick AWPs were largely static, once again contradicting the plaintiffs' theory of AWP "leap-frogging". Warrick AWPs have generally been static through most of the class period. Medispan data indicate that no AWP of Warrick's albuterol has been changed since 1995. Moreover, Warrick's AWPs did not respond to significant changes in the competitive environment, including the introduction of several new products, some of which garnered substantial shares of sales after their introduction. For instance, Warrick did not adjust its AWP for albuterol 0.5% in the face of Nephron's entry and a declining market share after 2002. Exhibit 5A is a chart of the sales

[3] I note that the median shown here is not one that is available from any published source; rather it is one that I have calculated as the median unit price AWP as reported by Medispan for all generic products of similar product description and strength. Although reimbursement for generic albuterol could theoretically depend upon AWP of Proventil—its branded counterpart—as a practical matter, the Proventil AWPs were substantially higher than the median generic AWP.

shares for albuterol 0.5% from 2000 to 2004.[4] While Warrick's share is relatively large, Warrick does appear to be losing share to Nephron after it apparently enters the market in late 2001. Yet, despite Nephron's entry at a higher AWP, and the loss of market share, Warrick did not increase its own AWP, as can be seen in Exhibit 5B. Moreover, Warrick's AWP is among the lowest of those firms with substantial market shares. Similarly, Exhibit 6A shows the sales shares for albuterol 0.083%. Again, Warrick has a large market share that is declining, and a static AWP, as can be seen in Exhibit 6B. Moreover, one can also see, in comparing Exhibits 6A and 6B, that Nephron lowered its AWP in 2002 and its market share increased. In short, the evidence on AWPs is utterly at odds with the plaintiffs' theory that Schering and Warrick "inflated" AWPs to drive share.

D. Dr. Hartman's Suggestion of a "Tacit Nash Equilibrium" is Both Unsupported and Inconsistent with the Plaintiff's Theories of AWP Manipulation to Compete for Market Share

41. Dr. Hartman has conceded expressly that no individual generic manufacturer has any incentive to inflate its AWP. But, in what is arguably the most remarkable portion of his Supplemental Declaration of April 2006, and in a complete departure from the plaintiffs' longstanding theories of the case, Dr. Hartman seems to suggest, rather, that the AWP inflation involved a collusive scheme on the part of Defendants, and perhaps others. According to his new theory of the case, "all generic manufacturers of a given drug have the incentive to maintain the median AWP as high as possible, in order to increase the "spreads" of all manufacturers relative to potential alternative therapeutic competitors." He also refers to the observed AWPs as being a "tacit Nash equilibrium." It may be useful to debunk any

[4] Exhibits 5A, 5B, 6A, 6B, and 6C also show the AWPs and sales shares for branded versions of the albuterol products.

misimpression created by this unnecessary misuse of economic jargon. In the simplest terms, a Nash equilibrium is just a state of affairs in which no participant has any incentive to modify his or her behavior given the behavior of every other participant. Therefore, calling a given marketplace outcome a Nash equilibrium is merely stating the obvious; any sustainable marketplace outcome is such an equilibrium. And, the use of the emotive word "tacit" adds no further meaning to this. To the extent that Dr. Hartman's musings are of any relevance whatsoever, it can only be because of a suggestion that the observed outcome is a Nash equilibrium that arose from tacit collusion rather than from competitive forces. Apparently the plaintiffs, at this stage, seek to enunciate a theory of collusive behavior regarding AWPs, despite Judge Saris's view that the plaintiffs' "key" allegation was that manufacturers compete rather than conspire with each other.

42. Unfortunately, this theory is no more consistent with the economic incentives facing the manufacturers than is the plaintiff's earlier version. That is because a higher median AWP cannot act as an incentive to the pharmacist not to dispense a competing "therapeutic alternative" to the prescribed generic drug: as I have already explained, the pharmacist ***does not have the option*** to substitute a completely different drug for the drug prescribed by the physician. So, for example, a pharmacist cannot dispense Singulair to fill a prescription for albuterol even though both can be used to treat asthma. The pharmacist may only choose which version of albuterol she or he will dispense. Thus, the notion that generic manufacturers of albuterol might collude or coordinate to make albuterol's AWP or "spread" attractive relative to *therapeutic* alternatives simply makes no economic sense. Prescriptions for albuterol (or its branded versions) will not respond to such manipulation of AWP or

"spread," because physicians have no pecuniary interest in the spread or AWP, and pharmacies can only dispense what is prescribed!

43. In any event, tacit collusion is an unlikely explanation for the observed marketplace outcomes. The AWP data that I have seen—as well as marketplace realities—are inconsistent with the observed outcomes' being the result of tacit collusion. This is unsurprising, because the economic underpinnings of any theory of tacit collusion are well known: the parties must be able to tacitly agree readily on an appropriate level for AWP; the parties must be able to tacitly agree readily on the degree to which deviations from the agreed price will be deemed permissible; and, there must be an effective way to accomplish targeted punishment of such deviations. None of those conditions are met here.

44. To begin with, the parties must agree that elevated AWPs are in their common best interest. Dr. Hartman appears simply to assume that this is the case. In fact, it is not. As I have explained, products like albuterol which are prescribed by physicians and dispensed by pharmacies present no particular incentive for their manufacturers to seek higher AWPs. Higher AWPs do not exert economic influence over prescribing decisions for albuterol, and higher AWPs do not benefit any one generic manufacturer at the expense of the others.

45. Even in the case of products prescribed and dispensed by physicians, generic manufacturers' incentives are neither self-evident nor necessarily aligned across manufacturers. Even if AWPs were elevated with a view towards shifting share from therapeutic substitutes, it is by no means clear that all—or even most—of the generic manufacturers of the molecule would

regard that with equal favor. Of course, all of this remains purely hypothetical; Dr. Hartman has yet to furnish any analysis showing that such therapeutic substitution could even be realistic for any of the products at issue. Nor has he provided any evidence of collusion – tacit or otherwise – or any incentive to collude. In fact, manufacturers' incentives could easily be contrary to plaintiffs' theory. Among other things, their attitude towards such share diversion would depend upon their economic interest in those therapeutic substitutes. In light of this, it is inherently implausible to suggest that generic manufacturers could tacitly agree on the appropriate AWPs for a given molecule.

46. Moreover, as an empirical matter, the AWPs for a given product span a range; it is difficult to visualize a collusive scheme that permits a range of prices, because it is then intrinsically unclear whether a particular AWP is within or outside the "permissible" range and who, among the alleged tacit conspirators, will make that determination. It is even more difficult to visualize a method of targeted punishment of violations, assuming that the parties could even agree upon what constitutes a violation—and assuming they could overcome the inherent difficulties in changing a median value. What form might the punishment take and who bears the cost of imposing it? Without effective means of policing the putative agreement, tacit collusion is inherently untenable.

47. Dr. Hartman further opines that the set of AWPs for generic drugs "are themselves all artificially inflated to the extent that the branded AWP against which the generic AWPs are set, is artificially inflated." While it is generally true that generic AWPs are set in reference to branded AWPs, Dr. Hartman's suggestion that albuterol AWPs are high because they were

set in reference to an artificially inflated Proventil AWP has no basis in fact or logic, in large part because there is no basis to suppose that Proventil's AWP was artificially inflated in the first instance. As I have already pointed out, Proventil's AWP is formulaically related to its WAC, and over the class period, substantial amounts of Proventil were sold at prices at or near WAC (i.e., within the standard industry "prompt pay" discount of 2 percent from WAC); therefore, it would have been economically irrational for Schering to lower its list price (i.e., its WAC and AWP) for Proventil—quite apart from any AWP "manipulation"—precisely because a very sizeable proportion of Proventil's sales were made at or near list price. The WAC represents the closest thing to a "list price" in the branded pharmaceutical industry.

48. Again, even though it is reimbursed under Medicare Part B, Proventil is a self-administered drug purchased at pharmacies. Inflating its AWP makes no difference to physicians' economic incentives to prescribe it, so Schering had no economic incentive to engage in such inflation. Moreover, Proventil was in competition with other branded albuterol drugs, Ventolin and Airet, and Dr. Hartman himself concedes that "all drug manufacturers, particularly innovator drug manufacturers, use [list prices as signals] to strategically place drug products in the market." Thus, it was the competition between these branded products that would have set Proventil's pricing, not any AWP inflation scheme of the sort suggested by Dr. Hartman.

VII. There is Ample Public Knowledge on "Spreads" of the Magnitude of which the Plaintiffs Complain

A. Dr. Hartman's Theory

49. I turn now to another of the plaintiff's allegations regarding "spreads," the allegation that payors were unaware of the extent of these spreads and that they were, therefore, being "fooled" into paying much more for these products than they otherwise would have.

50. Again, it may help to summarize what Dr. Hartman has done. He has opined that the spreads on some of these products were huge, deserving the title "mega spreads," because of AWP manipulation, that payors such as Medicare and Medicaid and others were simply unaware of the size of these spreads, and that, had they been aware of them, they would have adjusted their reimbursement down sharply.

51. I have examined the issue and have reached two conclusions. First, as I have already pointed out, spreads can be high for reasons having nothing whatsoever to do with AWP manipulation. Second, it is ridiculous to suggest that payors were unaware of the magnitudes of these spreads. I have pointed in my declaration at the summary judgment phase to 33 different published sources, many government studies focused on the cost of reimbursement, that discuss spreads for drugs, including several that specifically discuss albuterol—the only Warrick product at issue—that are very much in line with the "spreads" Dr. Hartman calculates. Dr. Hartman himself, in his Direct Testimony, acknowledges public awareness of these "spreads." I find it incomprehensible that Dr. Hartman still maintains that payors were unaware of the magnitudes of the spreads in light of these publications.

52. Indeed, it appears that BCBS/MA, the lead plaintiff in this case and an obviously sophisticated party is not only aware of the existence and magnitude of spreads, but has contributed to the creation of spreads of the type Dr. Hartman refers to as "mega spreads" through aggressive price negotiations by its staff model HMO directly with pharmaceutical manufacturers who are defendants in this case. BCBS/MA has not changed its own reimbursement methodology to some basis other than AWP. Moreover, BCBS/MA is even now in the process of moving other parts of its business to an AWP-based system of reimbursement.

B. The State of Public Knowledge Was Inconsistent with "Spread Manipulation"

53. More generally, industry observers and participants were well aware of the implications of the interplay of supply and demand forces for the "spreads" that might obtain in the pharmaceutical industry. The plaintiff's theory of "AWP manipulation" or "spread manipulation" is especially perplexing in light of this public awareness. The essence of any theory of manipulation of the "spread" must be that the perpetrator successfully concealed the true magnitude of the "spread"; the question of what the government and other payors—the market participants of interest—knew or should have known is of paramount importance. But very sizeable "spreads" were publicly known to exist for albuterol sulfate, for instance, "spreads" certainly far greater than the levels that Dr. Hartman concludes represented the outside limits of the market's awareness or expectations regarding "spreads."

54. A substantial body of public knowledge—found in government publications as well as in commentaries by industry observers and participants—made it clear that very substantial

"spreads" existed between the AWPs and prices received in the distribution chain of many drugs, including Warrick's albuterol sulfate.

55. Government studies and other reports published in 1989, 1992, 1996, 1997, 1998, 1999, 2000, 2001, 2002, 2003 and 2004 exposed the existence of spreads as high as 99 percent of AWP.[5] If one defers to Dr. Hartman's preference for calculating them as percentages of "ASP" (which are inevitably going to appear much larger), this translates into a ***spread of 9,900 percent of "ASP."*** [6] Exhibit 9A lists some of the sources that report these spreads. Exhibit 9B shows these data as bar charts.

56. Exhibit 9A contains data from a range of studies, dating from 1996 to 2004, which report upon the spreads prevailing for albuterol sulfate; as early as 1996, spreads of 65 percent of AWP were reported by the OIG—spreads that are roughly *three times* the highest threshold

[5] Included in these reports are the "various OIG reports" that Dr. Hartman refers to himself. "Declaration of Raymond S. Hartman in Support of Plaintiffs' Claims of Liability and Calcu[l]ation of Damages," December 15, 2005, p. 16. There are at least 36 public documents that report spreads, at least 23 of which appear to report original results. See Exhibit 2 in my declaration, Declaration of Sumanth Addanki (March 21, 2006).. The manner in which the plaintiff's expert calculates, presents and discusses "spreads" is, at the very least, confusing. The problem with the plaintiff's apparent "spreads" based on "ASP" is that a good deal of the published literature that studies the spreads between "ASP" and AWP has expressed these quantities as percentages of AWP; comparing the plaintiff's numbers to these published benchmarks cannot be done without first converting all of the numbers to a common base—percentages of either "ASP" or AWP. Of some 36 publications containing information on spreads, 25 reported the spread on an AWP or "price" base, 3 reported the spread on an "ASP" or "cost" base, and 8 reported spreads either in dollar terms or as a ratio. Thus, of the 28 publications that reported spreads in percentage terms, 89 percent of these reported the spread on an AWP base. Similarly, of the 17 studies that apparently reported original research on spreads in percentage terms, 15 reported the spread on an AWP base, while only 2 reported spreads on an "ASP" base.

[6] See, e.g., "Medicaid Pharmacy: Actual Acquisition Cost of Generic Prescription Drug Products," Department of Health and Human Services, Office of Inspector General, August 1997, and "Medicaid Pharmacy – Actual Acquisition Cost of Brand Name Prescription Drug Products," Department of Health and Human Services, Office of Inspector General, August 2001.

espoused by Dr. Hartman.[7] These data are represented as a bar chart in Exhibit 9B. Indeed, the picture is even more striking if one re-calculates these spreads based on his preferred "percentage of 'ASP'" approach. In that case, the spreads reported as early as 1996 were nearly 190 percent of "ASP," which is over *six times* the 30 percent threshold that Dr. Hartman urges. Again, to suggest, in this context, that government, policy makers or industry participants could not have been aware of spreads larger than 30 percent of "ASP" is simply ridiculous. Such entities knew, or should have known, that the true spreads were substantially higher than that. By 1998, spreads as high as 85 percent of AWP, or ***about 550 percent of "ASP"*** were reported for albuterol, as shown in Exhibits 9A and 9B.

C. Reimbursement Is Set in a Larger Context

57. Given that these studies were obviously part of a broad public discussion, making it clear that there was quite widespread awareness of the differentials between AWPs and provider costs, one might well question why this awareness did not translate into changes in reimbursement rates (i.e., to shrink those "spreads" between reimbursement and provider acquisition costs). The answer is that governmental reimbursement rates for prescriptions drugs are set in a larger context, in which apparent "spreads" may be permitted to persist in the interest of better serving these programs' broader goals. For instance, Medicare's reimbursement for physician-administered drugs includes a payment for the drug as well as a fee for administering it and the government has been engaged for years in a debate with the health care community over the structure of this compensation. For example, HCFA concluded in 2000 that Medicare under-compensated physicians for their provision of drug administration

[7] The earliest study to report albuterol spreads was conducted from January 1, 1994 to February 28, 1995 but these results were not published until 1996. ("Suppliers' Acquisition Costs For Albuterol Sulfate," Department of Health and Human Services, Office of Inspector General, June 1996, OEI-03-94-00393. Def. Ex. 1065.)

services and that drug payments above physicians' acquisition costs were offsetting these shortfalls, making it economically feasible for physicians to continue to offer such services in their offices.[8] What this implies, of course, is that it is meaningless to speak of "but-for" reimbursement rates for these drugs in a vacuum. If the reimbursement rates for the drugs are lowered, unless other compensation rates for administration services are raised correspondingly, physicians will have less incentive to continue to provide these services in-office. This is a matter of simple economics: if the payment for a service falls short of the opportunity cost of providing it (i.e., the revenue that could be garnered from the best alternative use of the physician's time and facilities), the physician will cease to offer that service. Should this happen, more patients will have to travel to hospitals for such treatment in their outpatient departments, resulting in higher costs to the Medicare system, and higher co-payments by the patients as well as increased inconvenience, travel time, treatment time and the like.[9]

58. If, on the other hand, Medicare were to offset the reduced drug reimbursement rates by increasing its compensation for the administrative services involved, the effect would be similar: Medicare payments and beneficiary co-payments for the drugs might be lowered, but payments and co-payments for the provision of the associated services would be increased;

[8] "Reform of the Medicare Payment Methods for Cancer Chemotherapy," American Society of Clinical Oncology, May 2001, p. 10, ("It was not until 2000 that HCFA acknowledged for the first time that Medicare payments for chemotherapy administration are too low. HCFA also concluded that its efforts to reduce drug payments should be suspended until the administration payments were increased.")

[9] "Reform of the Medicare Payment Methods for Cancer Chemotherapy," American Society of Clinical Oncology, May 2001, p. 10, ("In 1991, when HCFA proposed to reduce drug payments to 85 percent of AWP, many of the comments opposing the reduction cited the 'shortfalls in chemotherapy administration payments' and warned that '[w]ithout adequate compensation…many physicians would perform the service in hospital outpatient departments at substantially higher costs.'")

the net result cannot be predicted without considerably more analysis.[10] A decrease in pharmaceutical reimbursement can be more than offset by an increase in administrative service fees; for an illustration of this, see Exhibit 10, which shows reimbursement under alternative schemes for a 30-day supply of albuterol in the Medicare program.

59. In sum, governmental reimbursement rates for the various components of programs like Medicare are not set in isolation but are set in the larger context of these programs' broader goals. It is overly simplistic to suggest that reimbursement rates for drugs could be lowered without offsetting increases in other aspects of Medicare reimbursement and costs. I have pointed out ample evidence that government policy makers were well aware that providers would be unwilling to participate in a voluntary system in which they would lose money on the provision of pharmaceuticals, and that there were sometimes substantial differences between reimbursement rates for drugs and the prices actually paid for them. These differences could persist because they were viewed simply as the cost of ensuring that adequate numbers of providers were willing to participate in the program, ensuring in turn that patients would have reasonable access to care under the program. Thus, for instance, the goal of providing beneficiaries with the desired levels of access to pharmacies and physicians may be best served by permitting reimbursement rates for prescription drugs to reflect substantial apparent "spreads."

[10] In fact, when Medicare did lower the reimbursement rate for prescription drugs effective January 1, 2005, they increased the dispensing fee paid to providers, in addition to adding furnishing and supplying fees. (Federal Register, August 8, 2005, pp. 45846-48.)

VIII. Damages

60. I have also reviewed Dr. Hartman's damage calculations based on his spread analysis. For his damages under Medicare, Dr. Hartman asserts that AWP should have equaled ASP for the accused drugs. As I have explained, this simply ignores the reality in which Medicare reimbursement is set. He then attempts to justify this by asserting that damages under Medicare are specified "by statute," which makes no sense because Medicare prescribes no such statutory damages. Dr. Hartman's contention that AWP should have equaled ASP pre-dates Judge Saris's ruling that the appropriate interpretation of "AWP" as used in the Medicare statute is the price actually charged by wholesalers. As I will explain below, his contention is just as invalid in light of Judge Saris's ruling as it was prior to the ruling.

61. In fact, the requirement that AWP equal ASP can only be even remotely sensible under the following assumptions: (1) Medicare would have reimbursed for the drugs at issue at providers' estimated acquisition cost ("EAC") and (2) "ASP" could reasonably be used as a proxy for "EAC." Neither assumption is valid, and Dr. Hartman offers neither empirical nor theoretical support for either of them.

62. First, the assumption that Medicare would have chosen to reimburse the accused products at provider acquisition cost is directly contrary to the history of Medicare reimbursement. To my knowledge, and Dr. Hartman offers no evidence to the contrary, Medicare has never reimbursed at acquisition cost. It used AWP-based measures for years in the face of abundant information that acquisition costs were substantially lower, and when it changed to an ASP-based form of reimbursement in 2005, it raised the fees for the dispensing of drugs such as albuterol. Indeed, total reimbursement for certain forms of albuterol appear to have

increased in 2005 in the ASP-based Medicare regime over reimbursement under the previous AWP-based regime. So, there is simply no empirical basis for Dr. Hartman's assumption that Medicare would in fact have reimbursed providers at their acquisition costs without changing other terms of reimbursement in some way.

63. The second assumption, that ASP is a good proxy for EAC, is simply not a good assumption because ASP is the price paid by wholesalers, and EAC is the price at which wholesalers sell the drug to providers. Therefore, it fails to account for the margins earned by intermediaries in the pharmaceutical industry, including wholesalers.

64. The fact is that insisting upon equating ASP with EAC leads to absurd conclusions. To begin with, there is only one AWP for any given drug NDC. Therefore, any reimbursement scheme that is tied to AWP, and many formulae are tied in that fashion, depends upon that one AWP. Note, further, that many reimbursement schemes pay providers and pharmacies an amount less than AWP. Indeed, other government programs themselves, such as Medicaid, reimburse at rates below the AWP.

65. The implications are immediate: if the "ASP" is what the manufacturer obtains for its sale of a given NDC, unless the remainder of the distribution chain is willing to suffer a loss on every single unit that it sells of that NDC, the AWP—only some fraction of which will be paid as reimbursement when the drug is dispensed—cannot possibly be as low as the "ASP." For example, if we know that the manufacturer's "ASP" for a unit sold is $2.00, the AWP cannot possibly equal $2.00, because if it did, and reimbursement is, say, at 90 percent of

AWP, or $1.80, the rest of the distribution chain—wholesaler, distributor, pharmacy/provider—would have to absorb a loss on every unit sold! No rational economic agent would even carry the product under these circumstances.

66. If one were, in fact, to impose the requirement that AWP equal "ASP" no pharmaceutical product on the market would pass the test for liability that this requirement logically implies. Most drugs sold in the market are sold at transaction prices that, on average, are substantially below AWP—at least 20 to 25 percent less than AWP for branded drugs (for drugs that are sold at list price) with substantially greater discounts for generics (or branded drugs that are subject to therapeutic competition and, therefore, discounted from list price). Therefore, by the plaintiffs' assumption of equality, nearly every single NDC of every single pharmaceutical product on the market would be liable. However, the plaintiffs themselves have noted that of the thousands of NDCs on the market, only the handful identified and accused here are subject to the alleged manipulation scheme. As a simple matter of economics and logic, the plaintiffs' assumption leads to a test that cannot discriminate those products that were subject to the alleged scheme from those that were not but, rather, simply declares that all products were liable. The assumption of equality cannot be valid under these circumstances and must be set aside.

67. In his damage calculations, Dr. Hartman attempts to disaggregate the sales of the accused Schering and Warrick products into various categories of payors in order to identify the volumes paid for by Medicare and Medicaid. Exhibit 974, which appears to be an attachment to a late iteration of Dr. Hartman's analysis, states that "[f]or both albuterol and

Proventil, NAMCS and NDTI data are unsuitable for the analysis" because these data "are constructed from physician office-based surveys which do not capture the NDCs used with nebulizers (durable medical equipment) that are at issue here." Based on this dismissal of the very same data source that he relies upon for his disaggregation of other products' sales, Dr. Hartman adopts the arbitrary rule that 58 percent of all sales of the relevant albuterol and Proventil NDCs were reimbursed by Medicare. In fact, however, his statement about the NDTI data is incorrect. The NDCs at issue here for Schering and Warrick are those relating to its 0.083% and 0.5% nebulizer products. I examined the data that Dr. Hartman claims were unsuitable and that found portions of the survey do, in fact, track these very products—Proventil and albuterol products in 0.083% and 0.5% concentrations. Based on these data, the portion of these drugs' sales for which Medicare is a payor—calculated in the same manner in which Dr. Hartman has estimated this percentage for other drugs—is markedly smaller than the figures he arrives at by his alternative *ad hoc* method.

IX. Additional Errors

68. In applying his "test" for liability to Schering's Proventil—a multi-source drug for most of the class period—Dr. Hartman calculates the "spreads" for his "test" using Proventil's "own" AWPs, despite the fact that Medicare reimbursement for a multi-source drug would have taken place, as Dr. Hartman himself acknowledges, at the median generic AWP. Indeed, his own calculations of damages for Proventil rely on reimbursement having taken place based on the median generic AWP, rather than Proventil's own AWP. A simple recalculation of the "spreads" for his liability test using the median generic AWPs that he himself espouses

shows that much of the "liability" that he ascribes to Proventil falls away, as shown in Table 1.

Table 1

Comparison of Dr. Hartman's "Spreads" For Proventil Using His "Own" and "Multi" AWPs
1991 - 2003

NDC	Drug Description	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003
		(Percent)												
"Spreads" Using "Own" AWPs[1]		(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(k)	(l)	(m)
00085133601	PROVENTIL INHALATION SOLUTION	%	%	%	%	%	%	%	%	%	%	%	%	23.7 %
00085020901	PROVENTIL SOLUTION .083MG/ML	18.0	39.4	53.8	29.6	33.9	35.8	32.5	24.2	26.5	25.1	38.9		
00085180601	PROVENTIL SOLUTION .083MG/ML												20.0	77.0
00085020802	PROVENTIL SOLUTION 5MG/ML	16.5	34.1	59.4	30.3	41.2	42.8	51.5	21.7	17.2	19.9	25.5	188.5	
"Spreads" Using "Multi" AWPs[1]														
00085133601	PROVENTIL INHALATION SOLUTION	%	%	%	%	%	%	%	%	%	%	%	%	-20.0 %
00085020901	PROVENTIL SOLUTION .083MG/ML	18.0	39.4	53.8	10.8	14.4	11.0	-1.5	-11.3	-15.6	-15.1	-12.2		
00085180601	PROVENTIL SOLUTION .083MG/ML												-28.6	-0.2
00085020802	PROVENTIL SOLUTION 5MG/ML	16.5	20.4	43.1	17.0	26.8	22.7	26.9	-1.9	-11.6	-9.6	-12.2	92.2	

Notes: -- "Spreads" are calculated according to Dr. Hartman's formula: (AWP-ASP)/ASP.
[1] "Own" and "Multi" AWPs were taken from Dr. Hartman's November 1, 2006 Direct Testimony Backup.

Source: Dr. Hartman's November 1, 2006 Direct Testimony Backup.

69. In calculating the "ASPs" that Dr. Hartman uses in his "spread"-based test for liability, he appears, perhaps inadvertently, to have included shipments of product that represented donations by Schering to patient assistance programs to benefit indigent patients.[11] This erroneous inclusion of such shipments—which reflect a "price" of zero to Schering—inevitably results in an understatement of the "ASP" and a overstatement of the "spread".

70. For instance, AmeriCares, just one of the charitable organizations through which Schering effects these donations, was the recipient of sizeable quantities of Temodar and Intron A during the class period. These shipments, included by Dr. Hartman in his "ASP" calculation, were virtually all associated with a zero price in Schering sales data, reflecting their charitable nature. I have recalculated Dr. Hartman's "spreads" omitting just the shipments of

[11] In his deposition, Schering's Art Monaghan testified that the "class of trade" code of "999" is used for special purposes like these. See Deposition of Art Monaghan, p. 23 (June 21, 2005).

free goods to AmeriCares, and the results are presented in Table 2. Strikingly, Dr. Hartman's "liability" findings for Temodar vanish entirely and the "spreads" on Intron A also contract. Needless to say, similar results can be expected if other such donations are also excluded. HDS, another organization through which Schering implements such patient assistance activity also appears to have accounted for sizeable shipments of free goods. The exclusion of such transactions would, again, help to correct Dr. Hartman's overstatement of "spreads".

Table 2

Comparison of Dr. Hartman's Spreads for Intron-A and Temodar With Spreads Excluding AmeriCares

2001-2004

Dr. Hartman's Schering-Plough Annual Spreads from Attachment G.4.c of His Direct Testimony

NDC	Drug	Description	2001	2002	2003	2004Q1
00085057102	Intron	INTRON A INJECTABLE 10MILLN IU	28.7%	23.3%	27.9%	
00085057106	Intron	INTRON A INJECTABLE 10MILLN IU				
00085111001	Intron	INTRON A INJECTABLE 18MILLN IU	36.6%	26.3%	31.0%	53.8%
00085028502	Intron	INTRON A INJECTABLE 25MILLN IU	29.6%	31.4%		
00085053901	Intron	INTRON A INJECTABLE 50MILLN IU	34.0%	27.5%	34.7%	35.8%
00085068901	Intron	INTRON A INJECTION 18 MIU				
00085125901	Temodar	TEMODAR 100MG	21.3%	27.4%	22.7%	24.9%
00085125902	Temodar	TEMODAR 100MG	25.4%	24.5%	29.3%	34.8%
00085124401	Temodar	TEMODAR 20MG	20.9%	22.8%	23.5%	31.7%
00085124402	Temodar	TEMODAR 20MG	25.6%	26.3%	27.9%	35.0%
00085125201	Temodar	TEMODAR 250MG	21.7%	21.8%	22.5%	25.6%
00085125202	Temodar	TEMODAR 250MG	34.6%	33.2%	48.9%	
00085124801	Temodar	TEMODAR 5MG	21.7%	21.5%	26.6%	23.8%
00085124802	Temodar	TEMODAR 5MG	24.5%	28.3%	30.1%	35.6%

Replication of Dr. Hartman's Spreads Excluding AmeriCares

NDC	Drug	Description	2001	2002	2003	2004Q1
00085057102	Intron	INTRON A INJECTABLE 10MILLN IU	27.1%	23.1%	26.5%	
00085057106	Intron	INTRON A INJECTABLE 10MILLN IU				
00085111001	Intron	INTRON A INJECTABLE 18MILLN IU	32.6%	23.7%	26.6%	34.8%
00085028502	Intron	INTRON A INJECTABLE 25MILLN IU	28.0%	28.9%		
00085053901	Intron	INTRON A INJECTABLE 50MILLN IU	31.5%	26.0%	32.4%	32.0%
00085068901	Intron	INTRON A INJECTION 18 MIU				
00085125901	Temodar	TEMODAR 100MG	20.9%	22.0%	22.2%	24.9%
00085125902	Temodar	TEMODAR 100MG	21.1%	21.9%	21.0%	23.7%
00085124401	Temodar	TEMODAR 20MG	20.9%	22.3%	20.8%	26.2%
00085124402	Temodar	TEMODAR 20MG	20.8%	22.0%	22.2%	23.6%
00085125201	Temodar	TEMODAR 250MG	21.7%	21.8%	21.5%	25.6%
00085125202	Temodar	TEMODAR 250MG	20.2%	18.3%	19.7%	
00085124801	Temodar	TEMODAR 5MG	21.1%	21.4%	21.9%	23.8%
00085124802	Temodar	TEMODAR 5MG	21.0%	22.1%	21.6%	20.9%

Notes: -- The six Intron-A NDCs above are those for which Dr. Hartman calculates damages in his Direct Testimony (see footnote 221, page 151 of "Direct Testimony of Raymond S. Hartman," November 1, 2006).
-- Outlined cells indicate where the spreads exceed Dr. Hartman's 30 percent yardstick.
-- All transactions with customer name "AMERICARES" that had a price of zero were dropped.
-- There was a single AmeriCares transaction with a non-zero price in the direct sales data. This occurred for Intron-A NDC 00085123501, and had a revenue of -1,957.5 dollars and a quantity of -5.

Sources: -- "Attachment G.4.c: Schering-Plough Annual Spreads" in "Direct Testimony of Raymond S. Hartman," November 1, 20(
-- Dr. Hartman's November 1, 2006 Direct Testimony Backup SAS programs and Excel files.
-- Dr. Hartman's December, 15 2005 Liability Backup SAS programs.
-- Schering-Plough sales data.

I declare under penalty of perjury that the foregoing is true and correct. Executed on December 1, 2006.

/s/ Sumanth Addanki
Sumanth Addanki

APPENDIX A: Reimbursement for multi-source drugs based on the median

71. For most of the class period, reimbursement for multi-source drugs under Medicare Part B was based on a uniform measure such as the median AWP for the group rather than on individual AWPs.[12] Given this, for most generic products, and certainly the generic products in this case, the plaintiffs' theory of AWP manipulation makes no economic sense whatsoever. That is because when reimbursement for generic drugs is linked, for instance, to the median generic AWP, no individual manufacturer has any incentive to attempt to "inflate" its AWP, because it gets no benefit from such inflation. Should the median AWP not change, the "inflation" has no effect at all. Should the median AWP rise because of the "inflation," there is no advantage to the manufacturer initiating the "inflation" in its AWP, because all generic competitors will be reimbursed at the new, higher, AWP. In this reimbursement scheme, there is simply no incentive to raise one's AWP, because no competitive advantage can result from such an action.

72. Even setting aside the lack of any economic incentive to do so, the plaintiffs' contention that generic manufacturers *could* meaningfully manipulate the reimbursement rate (e.g., the *median* AWP) is far-fetched indeed.[13] By their very definition, medians are difficult to change and a scheme such as that proposed by the plaintiffs would have to rely on a

[12] Reimbursement between 1998 and 2003 was at the lower of the lowest branded AWP and the median AWP for the group; as a practical matter, because branded AWPs are generally much higher than generic AWPs, the reimbursement was at the median generic AWP. See, e.g., 56 FR 59502, §405.517, November 25, 1991; 63 FR 58814, §405.517, November 2, 1998; and 70 FR 59974, §405.517, October 13, 2005.

[13] See "Third Amended Master Consolidated Class Action Complaint Amended to Comply with Court's Class Certification Order," ¶ 202, p. 56, ("[A]ny one generic manufacturer can only affect the median generic reimbursement AWP for a product.")

substantial degree of luck. A median is the middle value of a distribution of values ranked from lowest to highest. Unlike an average, the median does not change whenever one of the constituent values used to calculate it change. If a value above the median is increased, the median will not change. If a value below the median is reduced, the median will not change.

73. Moreover, if the values in the distribution are repeated, or, in this case, if more than one product has the same AWP, changes to the median are even less likely to ensue from a change in one of the constituent values. For example, if there were nine firms with the following distribution of prices, {10, 10, 10, 20, 20, 20, 30, 30, 30}, then the median price would be 20. If one of the firms pricing at 10, were to reduce its price to, say, 1, the distribution would become {1, 10, 10, 20, 20, 20, 30, 30, 30} and the median would still be 20. Alternatively, if one of the firms pricing at 10 were to raise its price to 30, the distribution would become {10, 10, 20, 20, 20, 30, 30, 30, 30} and the median price would still be 20. Finally, even if one of the firms pricing at 20 were to change its price, say to reduce it to 10, the median price would not change. The distribution in this case would become {10, 10, 10, 10, 20, 20, 30, 30, 30} and the median would still be 20. Even this simple example is sufficient to show that it is difficult to conceive of any scheme by which medians can be manipulated by a firm acting unilaterally.